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Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability MDL NO. 15-02641-PHX-DGC
Litigation

This Document Relates to:

FLORENCE BURES,

Plaintiff,

v.

C. R. BARD, INC., a foreign corporation,
and BARD PERIPHERAL VASCULAR
INC., an Arizona corporation,

Case No. CV-16-00137-PHX-DGC

**DEFENDANTS C. R. BARD, INC. AND
BARD PERIPHERAL VASCULAR,
INC.'S ANSWER AND AFFIRMATIVE
DEFENSES AND DEMAND FOR
TRIAL BY JURY**

Defendants C. R. Bard, Inc. (“Bard”) and Bard Peripheral Vascular, Inc. (“BPV”) (Bard and BPV are collectively “Defendants”) answer the Complaint (“Plaintiff’s Complaint”) of Plaintiff Florence Bures (“Plaintiff”) as follows:

INTRODUCTORY ALLEGATIONS

1. Defendants admit that Bard owns a facility where vena cava filters are manufactured, including filters under the trademarks G2®, G2®X, G2® Express, Eclipse™, Meridian™, and Denali™ Filter Systems. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters under the trademarks G2®, G2®X, G2® Express, Eclipse™, Meridian™, and Denali™ Filter Systems. The allegations contained in Paragraph 1 of Plaintiff’s Complaint referencing the Recovery® Cone contain no factual allegations directed at Defendants and, therefore, require no response. To the extent a response is required, those allegations are denied. Defendants deny any remaining allegations contained in Paragraph 1 of Plaintiff’s Complaint.

2. Defendants admit that Plaintiff has brought this civil action for damages but deny that Plaintiff has suffered any personal injuries caused by Defendants, deny that Defendants are liable to Plaintiff, and deny that Plaintiff is entitled to any damages from Defendants. Defendants deny any remaining allegations contained in Paragraph 2 of Plaintiff’s Complaint.

3. Defendants deny the allegations contained in Paragraph 3 of Plaintiff’s Complaint.

4. Defendants deny the allegations contained in Paragraph 4 of Plaintiff’s Complaint.

5. Defendants deny that any of its inferior vena cava filter products are unreasonably dangerous or defective in any manner. Defendants admit that Bard owns a facility where vena cava filters are manufactured. Defendants further admit that BPV designs,

1 sells, markets, and distributes inferior vena cava filters. Defendants deny any remaining
2 allegations contained in Paragraph 5 of Plaintiff's Complaint.

3 6. Defendants deny the allegations contained in Paragraph 6 of Plaintiff's
4 Complaint.

5 **PARTIES**

6 7. Defendants are without knowledge or information sufficient to form a belief as
7 to the truth of the allegations contained in Paragraph 7 of Plaintiff's Complaint and, therefore,
8 deny them.

9 8. Defendants are without knowledge or information sufficient to form a belief as
10 to the truth of the allegations contained in Paragraph 8 of Plaintiff's Complaint and, therefore,
11 deny them.

12 9. Defendants deny the allegations contained in Paragraph 9 of Plaintiff's
13 Complaint.

14 10. Defendants deny the allegations contained in Paragraph 10 of Plaintiff's
15 Complaint.

16 11. Defendants deny that Bard is a Delaware Corporation. Defendants admit that
17 Bard is a New Jersey Corporation. Defendants admit that Bard owns a facility where vena
18 cava filters are manufactured, including filters under the trademarks G2®, G2®X, G2®
19 Express, Eclipse™, Meridian™, and Denali™ Filter Systems. Defendants further admit that
20 Bard is authorized to do business, and does business, in the Commonwealth of Pennsylvania.
21 Defendants deny any remaining allegations contained in Paragraph 11 of Plaintiff's
22 Complaint.

23 12. Defendants admit that BPV is an Arizona Corporation. Defendants admit that
24 BPV is a wholly owned subsidiary of Bard. Defendants further admit that BPV designs,
25 sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold,
26 marketed, and distributed filters under the trademarks G2®, G2®X, G2® Express, Eclipse™,
27 Meridian™, and Denali™ Filter Systems. Defendants admit that BPV is authorized to do
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1 business, and does business, in the Commonwealth of Pennsylvania. Defendants deny any
2 remaining allegations contained in Paragraph 12 of Plaintiff's Complaint.

3 13. Defendants deny the allegations contained in Paragraph 13 of Plaintiff's
4 Complaint.

5 14. Defendants deny the allegations contained in Paragraph 14 of Plaintiff's
6 Complaint.

7 15. Defendants deny the allegations contained in Paragraph 15 of Plaintiff's
8 Complaint.

9 16. Paragraph 16 of Plaintiff's Complaint contains no factual allegations directed at
10 Defendants and, therefore, requires no response. To the extent a response is required,
11 Defendants deny those allegations.

12 17. Defendants admit that Bard owns a facility where vena cava filters are
13 manufactured. Defendants further admit that BPV designs, sells, markets, and distributes
14 inferior vena cava filters. Defendants deny any remaining allegations contained in
15 Paragraph 17 of Plaintiff's Complaint.

16 18. Defendants admit that Bard owns a facility where vena cava filters are
17 manufactured. Defendants further admit that BPV designs, sells, markets, and distributes
18 inferior vena cava filters. Defendants admit that inferior vena cava filters are intended to
19 prevent injury or death resulting from venous thrombosis and pulmonary embolism.
20 Defendants also admit that inferior vena cava filters may also be used to treat patients who
21 are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants
22 deny any remaining allegations contained in Paragraph 18 of Plaintiff's Complaint.

23 19. Defendants deny the allegations contained in Paragraph 19 of Plaintiff's
24 Complaint.

25 **JURISDICTION AND VENUE**

26 20. Regarding Paragraph 20 of Plaintiff's Complaint, Defendants do not contest
27 that the injuries and damages alleged within Plaintiff's Complaint exceed the jurisdictional
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1 limit of this Court. However, Defendants deny that they are liable to Plaintiff for any amount
 2 whatsoever and deny that Plaintiff has suffered any damages whatsoever. Defendants do not
 3 dispute that, based on the facts as alleged by Plaintiff, which have not been, and could not
 4 have been confirmed by Defendants, jurisdiction appears to be proper in the United States
 5 District Court for the Middle District of Pennsylvania.

6 21. Regarding Paragraph 21 of Plaintiff's Complaint, Defendants do not dispute
 7 that, based on the facts as alleged by Plaintiff, which have not been and could not have been
 8 confirmed by Defendants, venue appears to be proper in the United States District Court for
 9 the Middle District of Pennsylvania.

10 **GENERAL FACTUAL ALLEGATIONS**

11 22. Defendants lack knowledge or information sufficient to form a belief as to the
 12 truth of the allegation regarding the time frame when inferior vena cava filters were first
 13 introduced on the market or the identity of manufacturers of inferior vena cava filters.
 14 Defendants deny any remaining allegations of Paragraph 22 of Plaintiff's Complaint.

15 23. Defendants admit that inferior vena cava filters are intended to prevent injury or
 16 death resulting from venous thrombosis and pulmonary embolism. Defendants further admit
 17 that inferior vena cava filters may be designed for permanent placement, temporary
 18 placement, or both. Defendants deny any remaining allegations of Paragraph 23 of Plaintiff's
 19 Complaint.

20 24. Defendants admit that the inferior vena cava is a large vein that receives blood
 21 from the lower regions of the body and delivers it to the right atrium of the heart. Defendants
 22 further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to
 23 human health, including sometimes death. Defendants deny any remaining allegations of 24
 24 of Plaintiff's Complaint.

25 25. Defendants admit that patients at a high risk for developing deep vein
 26 thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy,
 27 including but not limited to the medications listed in Paragraph 25 of Plaintiff's Complaint.
 28

1 Defendants further admit that inferior vena cava filters may also be used to treat patients who
2 are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants
3 lack knowledge or information sufficient to form a belief as to the truth of any remaining
4 allegations contained in Paragraph 25 of Plaintiff's Complaint and, on that basis, deny them.

5 26. Defendants lack knowledge or information or information sufficient to form a
6 belief as to the truth of the allegation regarding the time frame when inferior vena cava filters
7 were first introduced on the market. Defendants also lack knowledge or information sufficient
8 to form a belief as to the truth of the allegation regarding doctors' use of permanent filters.
9 Defendants deny any remaining allegations contained in Paragraph 26 of Plaintiff's
10 Complaint.

11 27. Defendants deny the allegations contained in Paragraph 27 of Plaintiff's
12 Complaint.

13 28. Defendants deny the allegations contained in Paragraph 28 of Plaintiff's
14 Complaint.

15 29. Defendants lack knowledge or information sufficient to form a belief as to the
16 truth of the allegations regarding the medical community's concerns regarding the desirability
17 of a retrievable filter. Defendants deny any remaining allegations of Paragraph 29 of
18 Plaintiffs' Complaint.

19 30. Defendants lack knowledge or information sufficient to admit or deny the
20 allegations regarding the intent of any other manufacturers in developing inferior vena cava
21 filter products. Defendants deny any remaining allegations of Paragraph 30 of Plaintiffs'
22 Complaint.

23 31. Defendants admit that the Recovery® Filter was cleared by the FDA for
24 retrievable placement on July 25, 2003, pursuant to applications submitted under
25 Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining
26 allegations contained in Paragraph 31 of Plaintiff's Complaint.

1 32. Defendants deny the allegations contained in Paragraph 32 of Plaintiff's
2 Complaint.

3 33. Defendants deny the allegations contained in Paragraph 33 of Plaintiff's
4 Complaint.

5 34. Defendants deny the allegations contained in Paragraph 34 of Plaintiff's
6 Complaint.

7 35. Defendants deny the allegations contained in Paragraph 35 of Plaintiff's
8 Complaint, including all sub-parts thereof.

9 36. Defendants deny the allegations contained in Paragraph 36 of Plaintiff's
10 Complaint.

11 37. Defendants deny that the G2® Filter, G2®X, G2® Express, or Eclipse™ Filters
12 are unreasonably dangerous or defective in any manner. Defendants admit that, as part of
13 their continuing efforts to constantly evaluate the medical devices they sell, in conjunction
14 with the ever-changing state-of-the-art, they are continually striving to improve the life-
15 saving performance of those devices. The Eclipse™ Filter was developed in furtherance of
16 those efforts. Defendants deny any remaining allegations contained in Paragraph 37 of
17 Plaintiff's Complaint.

18 38. Defendants admit that the Eclipse™ Filter System was cleared by the United
19 States Food and Drug Administration pursuant to an application submitted under
20 Section 510(k) of the Food, Drug and Cosmetic Act in 2010. Defendants further admit that, as
21 part of their continuing efforts to constantly evaluate the medical devices they sell, in
22 conjunction with the ever-changing state-of-the-art, they are continually striving to improve
23 the life-saving performance of those devices. The Eclipse™ Filter, which was
24 electropolished, was developed in furtherance of those efforts. Defendants deny any
25 remaining allegations contained in Paragraph 38 of Plaintiff's Complaint.

26 39. Defendants deny the allegations contained in Paragraph 39 of Plaintiff's
27 Complaint.

1 40. Defendants deny the allegations contained in Paragraph 40 of Plaintiff's
2 Complaint.

3 41. Defendants deny the allegations contained in Paragraph 41 of Plaintiff's
4 Complaint.

5 42. Defendants deny the allegations contained in Paragraph 42 of Plaintiff's
6 Complaint.

7 43. Defendants incorporate by reference their responses to Paragraphs 1-42 of
8 Plaintiff's Complaint as if fully set forth herein.

9 44. Defendants deny the allegations contained in Paragraph 44 of Plaintiff's
10 Complaint.

11 45. Defendants deny the allegations contained in Paragraph 45 of Plaintiff's
12 Complaint.

13 46. Defendants deny the allegations contained in Paragraph 46 of Plaintiff's
14 Complaint.

15 47. Defendants deny the allegations contained in Paragraph 47 of Plaintiff's
16 Complaint.

17 48. Defendants deny the allegations contained in Paragraph 48 of Plaintiff's
18 Complaint.

19 **FIRST CAUSE OF ACTION**

20 **STRICT LIABILITY MANUFACTURING DEFECT**

21 49. Defendants incorporate by reference their responses to Paragraphs 1-48 of
22 Plaintiff's Complaint as if fully set forth herein.

23 50. Defendants lack information or knowledge sufficient to form a belief as to the
24 truth of the allegations regarding the trade name of any inferior vena cava filter implanted in
25 Plaintiff and, therefore, deny them. Defendants admit that Bard owns a facility where vena
26 cava filters are manufactured. Defendants further admit that BPV designs, sells, markets, and
27
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1 distributes inferior vena cava filters. Defendants deny any remaining allegations contained in
2 Paragraph 50 of Plaintiff's Complaint.

3 51. Defendants deny the allegations contained in Paragraph 51 of Plaintiff's
4 Complaint.

5 52. Defendants deny the allegations contained in Paragraph 52 of Plaintiff's
6 Complaint.

7 53. Defendants deny the allegations contained in Paragraph 53 of Plaintiff's
8 Complaint.

9 Furthermore, responding to the unnumbered Paragraph following Paragraph 53 and
10 beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph.

11 **SECOND CAUSE OF ACTION**

12 **STRICT LIABILITY FAILURE TO WARN**

13 54. Defendants incorporate by reference their responses to Paragraphs 1-53 of
14 Plaintiff's Complaint as if fully set forth herein.

15 55. Defendants admit that Bard owns a facility where vena cava filters are
16 manufactured. Defendants further admit that BPV designs, sells, markets, and distributes
17 inferior vena cava filters. Defendants deny any remaining allegations contained in
18 Paragraph 55 of Plaintiff's Complaint.

19 56. Defendants deny the allegations contained in Paragraph 56 of Plaintiff's
20 Complaint.

21 57. Defendants admit that there are various well-documented complications that
22 may occur as the result of use of any inferior vena cava filter. Defendants further admit that it
23 is well documented that many instances of known complications with inferior vena cava filter
24 use result in no complications whatsoever, but, rather, are completely asymptomatic. By way
25 of further response, Bard states that there are incidents related to the occurrence of known
26 complications associated with every manufacturer of inferior vena cava filters. Defendants
27 deny any remaining allegations contained in Paragraph 57 of Plaintiff's Complaint.
28

1 58. Defendants deny the allegations contained in Paragraph 58 of Plaintiff's
2 Complaint.

3 59. Defendants deny the allegations contained in Paragraph 59 of Plaintiff's
4 Complaint.

5 60. Defendants deny the allegations contained in Paragraph 60 of Plaintiff's
6 Complaint.

7 61. Defendants deny the allegations contained in Paragraph 61 of Plaintiff's
8 Complaint.

9 62. Defendants deny the allegations contained in Paragraph 62 of Plaintiff's
10 Complaint.

11 63. Defendants deny the allegations contained in Paragraph 63 of Plaintiff's
12 Complaint.

13 64. Defendants deny the allegations contained in Paragraph 64 of Plaintiff's
14 Complaint.

15 Furthermore, responding to the unnumbered Paragraph following Paragraph 64 and
16 beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph.

17 **THIRD CAUSE OF ACTION**

18 **STRICT LIABILITY DESIGN DEFECT**

19 65. Defendants incorporate by reference their responses to Paragraphs 1-64 of
20 Plaintiff's Complaint as if fully set forth herein.

21 66. Defendants lack information or knowledge sufficient to form a belief as to the
22 truth of the allegations regarding the trade name of any inferior vena cava filter implanted in
23 Plaintiff and, therefore, deny them. Defendants admit that Bard owns a facility where vena
24 cava filters are manufactured. Defendants further admit that BPV designs, sells, markets, and
25 distributes inferior vena cava filters. Defendants deny any remaining allegations contained in
26 Paragraph 66 of Plaintiff's Complaint.
27
28

1 67. Defendants lack information or knowledge sufficient to form a belief as to the
2 truth of the allegations contained in Paragraph 67 of Plaintiff's Complaint and, therefore,
3 deny them.

4 68. Defendants deny the allegations contained in Paragraph 68 of Plaintiff's
5 Complaint.

6 69. Defendants deny the allegations contained in Paragraph 69 of Plaintiff's
7 Complaint.

8 70. Defendants deny the allegations contained in Paragraph 70 of Plaintiff's
9 Complaint.

10 71. Defendants deny the allegations contained in Paragraph 71 of Plaintiff's
11 Complaint.

12 72. Defendants deny the allegations contained in Paragraph 72 of Plaintiff's
13 Complaint.

14 73. Defendants deny the allegations contained in Paragraph 73 of Plaintiff's
15 Complaint.

16 74. Defendants deny the allegations contained in Paragraph 74 of Plaintiff's
17 Complaint.

18 Furthermore, responding to the unnumbered Paragraph following Paragraph 74 and
19 beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph.

20 **FOURTH CAUSE OF ACTION**

21 **NEGLIGENCE – DESIGN**

22 75. Defendants incorporate by reference their responses to Paragraphs 1-74 of
23 Plaintiff's Complaint as if fully set forth herein.

24 76. Defendants deny the allegations contained in Paragraph 76 of Plaintiff's
25 Complaint, including all sub-parts thereof.

26 77. Defendants deny the allegations contained in Paragraph 77 of Plaintiff's
27 Complaint, including all sub-parts thereof.

1 78. The allegations contained in Paragraph 78 of Plaintiff's Complaint regarding
2 Defendants' legal duties are conclusions of law, to which no response is required. To the
3 extent a response is required, Defendants deny those allegations.

4 79. Defendants deny the allegations contained in Paragraph 79 of Plaintiff's
5 Complaint, including all sub-parts thereof.

6 80. Defendants deny the allegations contained in Paragraph 80 of Plaintiff's
7 Complaint.

8 Furthermore, responding to the unnumbered Paragraph following Paragraph 80 and
9 beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph.

10 **FIFTH CAUSE OF ACTION**

11 **NEGLIGENCE – MANUFACTURE**

12 81. Defendants incorporate by reference their responses to Paragraphs 1-80 of
13 Plaintiff's Complaint as if fully set forth herein.

14 82. The allegations contained in Paragraph 82 of Plaintiff's Complaint regarding
15 Defendants' legal duties are conclusions of law, to which no response is required. To the
16 extent a response is required, Defendants deny those allegations.

17 83. Defendants deny the allegations contained in Paragraph 83 of Plaintiff's
18 Complaint, including all sub-parts thereof.

19 84. Defendants deny the allegations contained in Paragraph 84 of Plaintiff's
20 Complaint.

21 Furthermore, responding to the unnumbered Paragraph following Paragraph 84 and
22 beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph.

23 **SIXTH CAUSE OF ACTION**

24 **NEGLIGENCE – FAILURE TO RECALL/RETROFIT**

25 85. Defendants incorporate by reference their responses to Paragraphs 1-84 of
26 Plaintiff's Complaint as if fully set forth herein.

86. Defendants deny the allegations contained in Paragraph 86 of Plaintiff's Complaint.

87. Defendants deny the allegations contained in Paragraph 87 of Plaintiff's Complaint.

88. Defendants deny the allegations contained in Paragraph 88 of Plaintiff's Complaint.

89. Defendants deny the allegations contained in Paragraph 89 of Plaintiff's Complaint.

90. The allegations contained in Paragraph 90 of Plaintiff's Complaint regarding Defendants' legal duties are conclusions of law, to which no response is required. To the extent a response is required, Defendants deny those allegations.

91. Defendants deny the allegations contained in Paragraph 91 of Plaintiff's Complaint.

92. Defendants deny the allegations contained in Paragraph 92 of Plaintiff's Complaint.

Furthermore, responding to the unnumbered Paragraph following Paragraph 92 and beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph.

SEVENTH CAUSE OF ACTION

NEGLIGENCE FAILURE TO WARN

93. Defendants incorporate by reference their responses to Paragraphs 1-92 of Plaintiff's Complaint as if fully set forth herein.

94. Defendants deny the allegations contained in Paragraph 94 of Plaintiff's Complaint.

95. Defendants deny the allegations contained in Paragraph 95 of Plaintiff's Complaint.

96. Defendants deny the allegations contained in Paragraph 96 of Plaintiff's Complaint.

1 97. Defendants deny the allegations contained in Paragraph 97 of Plaintiff's
2 Complaint.

3 98. The allegations contained in Paragraph 98 of Plaintiff's Complaint regarding
4 Defendants' legal duties are conclusions of law, to which no response is required. To the
5 extent a response is required, Defendants deny those allegations.

6 99. Defendants deny the allegations contained in Paragraph 99 of Plaintiff's
7 Complaint.

8 100. Defendants deny the allegations contained in Paragraph 100 of Plaintiff's
9 Complaint.

10 Furthermore, responding to the unnumbered Paragraph following Paragraph 100 and
11 beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph.

12 **EIGHTH CAUSE OF ACTION**

13 **NEGLIGENT MISREPRESENTATION**

14 101. Defendants incorporate by reference their responses to Paragraphs 1-100 of
15 Plaintiff's Complaint as if fully set forth herein.

16 102. Defendants deny the allegations contained in Paragraph 102 of Plaintiff's
17 Complaint.

18 103. Defendants deny the allegations contained in Paragraph 103 of Plaintiff's
19 Complaint.

20 104. The allegations contained in Paragraph 104 of Plaintiff's Complaint regarding
21 Defendants' legal duties are conclusions of law, to which no response is required. To the
22 extent a response is required, Defendants deny those allegations.

23 105. Defendants deny the allegations contained in Paragraph 105 of Plaintiff's
24 Complaint.

25 106. Defendants deny the allegations contained in Paragraph 106 of Plaintiff's
26 Complaint.

1 107. Defendants deny the allegations contained in Paragraph 107 of Plaintiff's
2 Complaint.

3 108. Defendants deny the allegations contained in Paragraph 108 of Plaintiff's
4 Complaint.

5 109. The allegations contained in Paragraph 109 of Plaintiff's Complaint regarding
6 Defendants' legal duties are conclusions of law, to which no response is required. To the
7 extent a response is required, Defendants deny those allegations.

8 110. Defendants deny the allegations contained in Paragraph 110 of Plaintiff's
9 Complaint.

10 111. Defendants deny the allegations contained in Paragraph 111 of Plaintiff's
11 Complaint.

12 Furthermore, responding to the unnumbered Paragraph following Paragraph 111 and
13 beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph.

14 **NINTH CAUSE OF ACTION**

15 **NEGLIGENCE *PER SE***

16 112. Defendants incorporate by reference their responses to Paragraphs 1-111 of
17 Plaintiff's Complaint as if fully set forth herein.

18 113. The allegations contained in Paragraph 113 of Plaintiff's Complaint are
19 conclusions of law, to which no response is required. To the extent a response is required,
20 Defendants deny those allegations.

21 114. Defendants deny the allegations contained in Paragraph 114 of Plaintiff's
22 Complaint, including all sub-parts thereof.

23 115. The allegations contained in Paragraph 115 of Plaintiff's Complaint are not
24 directed at Defendants and, therefore, require no response. To the extent a response is
25 required, Defendants deny those allegations.

1 116. The allegations contained in Paragraph 116 of Plaintiff's Complaint are
2 conclusions of law, to which no response is required. To the extent a response is required,
3 Defendants deny those allegations.

4 117. Defendants deny the allegations contained in Paragraph 117 of Plaintiff's
5 Complaint.

6 Furthermore, responding to the unnumbered Paragraph following Paragraph 117 and
7 beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph.

8 **TENTH CAUSE OF ACTION**

9 **BREACH OF EXPRESS WARRANTY**

10 118. Defendants incorporate by reference their responses to Paragraphs 1-117 of
11 Plaintiff's Complaint as if fully set forth herein.

12 119. Defendants are without knowledge or information sufficient to form a belief as
13 to the truth of the allegations contained in Paragraph 119 of Plaintiff's Complaint and,
14 therefore, deny those allegations.

15 120. The allegations contained in Paragraph 120 of Plaintiff's Complaint are
16 conclusions of law, to which no response is required. To the extent a response is required,
17 Defendants deny those allegations.

18 121. Defendants deny the allegations contained in Paragraph 121 of Plaintiff's
19 Complaint.

20 122. Defendants deny the allegations contained in Paragraph 122 of Plaintiff's
21 Complaint, including all sub-parts thereof.

22 123. Defendants deny the allegations contained in Paragraph 123 of Plaintiff's
23 Complaint.

24 Furthermore, responding to the unnumbered Paragraph following Paragraph 123 and
25 beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph.

ELEVENTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

124. Defendants incorporate by reference their responses to Paragraphs 1-123 of Plaintiff's Complaint as if fully set forth herein.

125. Defendants deny the allegations contained in Paragraph 125 of Plaintiff's Complaint.

126. Defendants deny the allegations contained in Paragraph 126 of Plaintiff's Complaint, including all sub-parts thereof.

127. Defendants deny the allegations contained in Paragraph 127 of Plaintiff's Complaint.

Furthermore, responding to the unnumbered Paragraph following Paragraph 127 and beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph.

TWELFTH CAUSE OF ACTION

FRAUDULENT MISREPRESENTATION

128. Defendants incorporate by reference their responses to Paragraphs 1-127 of Plaintiff's Complaint as if fully set forth herein.

129. Defendants deny the allegations contained in Paragraph 129 of Plaintiff's Complaint, including all sub-parts thereof.

130. Defendants deny the allegations contained in Paragraph 130 of Plaintiff's Complaint, as stated.

131. Defendants deny the allegations contained in Paragraph 131 of Plaintiff's Complaint.

132. Defendants deny the allegations contained in Paragraph 132 of Plaintiff's Complaint.

133. Defendants deny the allegations contained in Paragraph 133 of Plaintiff's Complaint.

1 134. Defendants deny the allegations contained in Paragraph 134 of Plaintiff's
2 Complaint.

3 135. Defendants deny the allegations contained in Paragraph 135 of Plaintiff's
4 Complaint.

5 136. Defendants deny the allegations contained in Paragraph 136 of Plaintiff's
6 Complaint.

7 137. Defendants deny the allegations contained in Paragraph 137 of Plaintiff's
8 Complaint.

9 138. Defendants deny the allegations contained in Paragraph 138 of Plaintiff's
10 Complaint.

11 139. Defendants deny the allegations contained in Paragraph 139 of Plaintiff's
12 Complaint.

13 140. Defendants deny the allegations contained in Paragraph 140 of Plaintiff's
14 Complaint.

15 141. Defendants deny the allegations contained in Paragraph 141 of Plaintiff's
16 Complaint.

17 142. Defendants deny the allegations contained in Paragraph 142 of Plaintiff's
18 Complaint.

19 Furthermore, responding to the unnumbered Paragraph following Paragraph 142 and
20 beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph.

21 **THIRTEENTH CAUSE OF ACTION**

22 **FRAUDULENT CONCEALMENT**

23 143. Defendants incorporate by reference their responses to Paragraphs 1-142 of
24 Plaintiff's Complaint as if fully set forth herein.

25 144. Defendants deny the allegations contained in Paragraph 144 of Plaintiff's
26 Complaint.

1 145. Defendants deny the allegations contained in Paragraph 145 of Plaintiff's
2 Complaint, including all sub-parts thereof.

3 146. Defendants deny the allegations contained in Paragraph 146 of Plaintiff's
4 Complaint.

5 147. Defendants deny the allegations contained in Paragraph 147 of Plaintiff's
6 Complaint.

7 148. Defendants deny the allegations contained in Paragraph 148 of Plaintiff's
8 Complaint.

9 149. Defendants deny the allegations contained in Paragraph 149 of Plaintiff's
10 Complaint.

11 Furthermore, responding to the unnumbered Paragraph following Paragraph 149 and
12 beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph.

13 **FOURTEENTH CAUSE OF ACTION**

14 **VIOLATION OF APPLICABLE STATE LAWS PROHIBITING CONSUMER**

15 **FRAUD AND UNFAIR DECEPTIVE TRADE PRACTICES**

16 150. Defendants incorporate by reference their responses to Paragraphs 1-149 of
17 Plaintiff's Complaint as if fully set forth herein.

18 151. The allegations contained in Paragraph 151 regarding Defendants' legal duties
19 are conclusions of law, to which no response is required. To the extent a response is required,
20 Defendants deny those allegations.

21 152. Defendants deny the allegations contained in Paragraph 152 of Plaintiff's
22 Complaint.

23 153. Defendants deny the allegations contained in Paragraph 153 of Plaintiff's
24 Complaint.

25 154. Defendants deny the allegations contained in Paragraph 154 of Plaintiff's
26 Complaint.

1 155. Defendants deny the allegations contained in Paragraph 155 of Plaintiff's
2 Complaint.

3 156. Defendants deny the allegations contained in Paragraph 156 of Plaintiff's
4 Complaint.

5 157. Defendants deny the allegations contained in Paragraph 157 of Plaintiff's
6 Complaint.

7 158. Defendants deny the allegations contained in Paragraph 158 of Plaintiff's
8 Complaint.

9 159. Defendants deny the allegations contained in Paragraph 159 of Plaintiff's
10 Complaint.

11 160. Defendants deny the allegations contained in Paragraph 160 of Plaintiff's
12 Complaint.

13 161. Defendants deny the allegations contained in Paragraph 161 of Plaintiff's
14 Complaint.

15 162. Defendants deny the allegations contained in Paragraph 162 of Plaintiff's
16 Complaint.

17 Furthermore, responding to the unnumbered Paragraph following Paragraph 162 and
18 beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph.

19 **PUNITIVE DAMAGES ALLEGATIONS**

20 163. Defendants incorporate by reference their responses to Paragraphs 1-162 of
21 Plaintiff's Complaint as if fully set forth herein.

22 164. Defendants deny the allegations contained in Paragraph 164 of Plaintiff's
23 Complaint.

24 165. Defendants deny the allegations contained in Paragraph 165 of Plaintiff's
25 Complaint.

26 166. Defendants deny the allegations contained in Paragraph 166 of Plaintiff's
27 Complaint.

1 167. Defendants deny the allegations contained in Paragraph 167 of Plaintiff's
2 Complaint.

3 168. Defendants deny the allegations contained in Paragraph 168 of Plaintiff's
4 Complaint.

5 169. Defendants deny the allegations contained in Paragraph 169 of Plaintiff's
6 Complaint.

7 170. Defendants deny the allegations contained in Paragraph 170 of Plaintiff's
8 Complaint.

9 171. Defendants deny the allegations contained in Paragraph 171 of Plaintiff's
10 Complaint.

11 172. Defendants deny the allegations contained in Paragraph 172 of Plaintiff's
12 Complaint.

13 173. Defendants deny the allegations contained in Paragraph 173 of Plaintiff's
14 Complaint.

15 **PRAYER FOR RELIEF**

16 Furthermore, responding to the unnumbered Paragraph, including sub-parts, following
17 the heading "PRAYER FOR RELIEF" and beginning "WHEREFORE," Defendants deny the
18 allegations contained in such Paragraph and all sub-parts thereof.

19 Defendants further deny each and every allegation not specifically admitted herein.

20 **DEFENSES**

21 Defendants allege as affirmative defenses the following:

22 1. Plaintiff's Complaint filed herein fails to state a claim or claims upon which
23 relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

24 2. The sole proximate cause of Plaintiff's damages, if any were sustained, was the
25 negligence of a person or persons or entity for whose acts or omissions Defendants were and
26 are in no way liable.

1 3. Plaintiff's claims are barred, in whole or in part, by the applicable statutes of
2 limitations and/or statute of repose.

3 4. If Plaintiff has been damaged, which Defendants deny, any recovery by
4 Plaintiff is barred to the extent Plaintiff voluntarily exposed herself to a known risk and/or
5 failed to mitigate her alleged damages. To the extent Plaintiff has failed to mitigate her
6 alleged damages, any recovery shall not include alleged damages that could have been
7 avoided by reasonable care and diligence.

8 5. If Plaintiff has been damaged, which Defendants deny, such damages were
9 caused by the negligence or fault of Plaintiff.

10 6. If Plaintiff has been damaged, which Defendants deny, such damages were
11 caused by the negligence or fault of persons and/or entities for whose conduct Defendants are
12 not legally responsible.

13 7. The conduct of Defendants and the subject product at all times conformed to
14 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*, and other pertinent
15 federal statutes and regulations. Accordingly, Plaintiff's claims are barred, in whole or in
16 part, under the doctrine of federal preemption, and granting the relief requested would
17 impermissibly infringe upon and conflict with federal laws, regulations, and policies in
18 violation of the Supremacy Clause of the United States Constitution.

19 8. If Plaintiff has been damaged, which Defendants deny, such damages were
20 caused by unforeseeable, independent, intervening, and/or superseding events for which
21 Defendants are not legally responsible.

22 9. There was no defect in the product at issue with the result that Plaintiff is not
23 entitled to recover against Defendants in this cause.

24 10. If there were any defect in the products – and Defendants deny that there were
25 any defects – nevertheless, there was no causal connection between any alleged defect and
26 the product on the one hand and any damage to Plaintiff on the other with the result that
27 Plaintiff is not entitled to recover against Defendants in this cause.
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1 11. Plaintiff's injuries, losses or damages, if any, were caused by or contributed to
2 by other persons or entities that are severally liable for all or part of Plaintiff's alleged
3 injuries, losses or damages. If Defendants are held liable to Plaintiff, which liability is
4 specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification,
5 either in whole or in part, from all persons or entities whose negligence or fault proximately
6 caused or contributed to cause Plaintiff's alleged damages.

7 12. Plaintiff's claims are barred to the extent that the injuries alleged in the
8 Plaintiff's Complaint were caused by the abuse, misuse, abnormal use, or use of the product
9 at issue in a manner not intended by Defendants and over which Defendants had no control.

10 13. Plaintiff's claims are barred to the extent that the injuries alleged in the
11 Plaintiff's Complaint were caused by a substantial change in the product after leaving the
12 possession, custody, and control of Defendants.

13 14. Plaintiff's breach of warranty claims are barred because: (1) Defendants did not
14 make any warranties, express or implied, to Plaintiff; (2) there was a lack of privity between
15 Defendants and Plaintiff; and (3) notice of an alleged breach was not given to the seller or
16 Defendants.

17 15. Plaintiff's claims for breach of implied warranty must fail because the product
18 was not used for its ordinary purpose.

19 16. Defendants neither had nor breached any alleged duty to warn with respect to
20 the product, with the result that Plaintiff is not entitled to recover in this cause.

21 17. Plaintiff's claims are barred by Defendants' dissemination of legally adequate
22 warnings and instructions to learned intermediaries.

23 18. At all relevant times, herein, Plaintiff's physicians were in the position of
24 sophisticated purchasers, fully knowledgeable and informed with respect to the risks and
25 benefits of the subject product.

26 19. If Plaintiff has been damaged, which Defendants deny, the actions of persons or
27 entities for whose conduct Defendants are not legally responsible and the independent
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1 knowledge of these persons or entities of the risks inherent in the use of the product and other
2 independent causes, constitute an intervening and superseding cause of Plaintiff's alleged
3 damages.

4 20. To the extent that injuries and damages sustained by Plaintiff, as alleged in
5 Plaintiff's Complaint, were caused directly, solely, and proximately by sensitivities, medical
6 conditions, and idiosyncrasies peculiar to Plaintiff not found in the general public, they were
7 unknown, unknowable, or not reasonably foreseeable to Defendants.

8 21. Defendants believe, and upon that ground allege, that Plaintiff was advised of
9 the risks associated with the matters alleged in Plaintiff's Complaint and knowingly and
10 voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed
11 consent, release, waiver, or comparative fault, this conduct bars in whole or in part the
12 damages that Plaintiff seeks to recover herein.

13 22. At all relevant times during which the device at issue was designed, developed,
14 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
15 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
16 information, and instructions, all pursuant to generally recognized prevailing industry
17 standards and state-of-the-art in existence at the time.

18 23. Plaintiff's claims are barred because Plaintiff suffered no injury or damages as a
19 result of the alleged conduct and do not have any right, standing, or competency to maintain
20 claims for damages or other relief.

21 24. Plaintiff's claims are barred, in whole or in part, by the doctrines of waiver,
22 estoppel, and/or laches.

23 25. If Plaintiff suffered any damages or injuries, which is denied, Defendants state
24 that Plaintiff's recovery is barred, in whole or in part, or subject to reduction, under the
25 doctrines of contributory and/or comparative negligence.

26 26. In the further alternative, and only in the event that it is determined that
27 Plaintiff is entitled to recover against Defendants, recovery should be reduced in proportion to
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1 the degree or percentage of negligence, fault or exposure to products attributable to Plaintiff,
2 any other defendants, third-party defendants, or other persons, including any party immune
3 because bankruptcy renders them immune from further litigation, as well as any party, co-
4 defendant, or non-parties with whom Plaintiff has settled or may settle in the future.

5 27. Should Defendants be held liable to Plaintiff, which liability is specifically
6 denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiff
7 from all collateral sources.

8 28. Plaintiff's claims may be barred, in whole or in part, from seeking recovery
9 against Defendants pursuant to the doctrines of res judicata, collateral estoppel, release of
10 claims, and the prohibition on double recovery for the same injury.

11 29. The injuries and damages allegedly sustained by Plaintiff may be due to the
12 operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiff
13 over which Defendants had no control.

14 30. The conduct of Defendants and all activities with respect to the subject product
15 have been and are under the supervision of the Federal Food and Drug Administration
16 ("FDA"). Accordingly, this action, including any claims for monetary and/or injunctive relief,
17 is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

18 31. Defendants assert any and all defenses, claims, credits, offsets, or remedies
19 provided by the Restatements (Second and Third) of Torts and reserve the right to amend
20 their Answer to file such further pleadings as are necessary to preserve and assert such
21 defenses, claims, credits, offsets, or remedies.

22 32. The device at issue complied with any applicable product safety statute or
23 administrative regulation, and therefore Plaintiff's defective design and warnings-based
24 claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq.* and
25 comments thereto.

26 33. Plaintiff cannot show that any reasonable alternative design would have
27 rendered the Eclipse™ Filter as alleged in Plaintiff's Complaint to be safer overall under the
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1 Restatement (Third) of Product Liability § 2, cmt. f, nor could Defendants have known of any
2 alternative design that may be identified by Plaintiff.

3 34. The device at issue was not sold in a defective condition unreasonably
4 dangerous to the user or consumer, and therefore Plaintiff's claims are barred under the
5 Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and
6 comparable provisions of the Restatement (Third) of Torts (Products Liability).

7 35. At all relevant times during which the device at issue was designed, developed,
8 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
9 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
10 information, and instructions, all pursuant to generally recognized prevailing industry
11 standards and state-of-the-art in existence at the time.

12 36. Defendants specifically plead all affirmative defenses under the Uniform
13 Commercial Code ("UCC") now existing or which may arise in the future, including those
14 defenses provided by UCC §§ 2-607 and 2-709.

15 37. Plaintiff's alleged damages, if any, should be apportioned among all parties at
16 fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors
17 Act.

18 38. No act or omission of Defendants was malicious, willful, wanton, reckless, or
19 grossly negligent, and, therefore, any award of punitive damages is barred.

20 39. To the extent the claims asserted in Plaintiff's Complaint are based on a theory
21 providing for liability without proof of defect and proof of causation, the claims violate
22 Defendants' rights under the Constitution of the United States and analogous provisions of
23 the Pennsylvania Constitution.

24 40. To the extent Plaintiff seeks punitive damages, Defendants specifically
25 incorporate by reference any and all standards of limitations regarding the determination
26 and/or enforceability of punitive damages awards that arose in the decisions of *BMW of*
27 *No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool*

1 *Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct.
 2 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S.
 3 June 25, 2008) and their progeny as well as other similar cases under both federal and state
 4 law.

5 41. Any of Plaintiff's claims for punitive or exemplary damages violate, and are
 6 therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the
 7 Constitution of the United States of America, and similar provisions of the Pennsylvania
 8 Constitution, on grounds including the following:

- 9 (a) it is a violation of the Due Process and Equal Protection Clauses of the
 10 Fourteenth Amendment of the United States Constitution to impose punitive
 11 damages, which are penal in nature, against a civil defendant upon the plaintiffs
 12 satisfying a burden of proof which is less than the "beyond a reasonable doubt"
 13 burden of proof required in criminal cases;
- 14 (b) the procedures pursuant to which punitive damages are awarded may result in
 15 the award of joint and several judgments against multiple defendants for
 16 different alleged acts of wrongdoing, which infringes upon the Due Process and
 17 Equal Protection Clauses of the Fourteenth Amendment of the United States
 18 Constitution;
- 19 (c) the procedures to which punitive damages are awarded fail to provide a
 20 reasonable limit on the amount of the award against Defendants, which thereby
 21 violates the Due Process Clause of the Fourteenth Amendment of the United
 22 States Constitution;
- 23 (d) the procedures pursuant to which punitive damages are awarded fail to provide
 24 specific standards for the amount of the award of punitive damages which
 25 thereby violates the Due Process Clause of the Fourteenth Amendment of the
 26 United States Constitution;

1 (e) the procedures pursuant to which punitive damages are awarded result in the
2 imposition of different penalties for the same or similar acts, and thus violate
3 the Equal Protection Clause of the Fourteenth Amendment of the United States
4 Constitution;

5 (f) the procedures pursuant to which punitive damages are awarded permit the
6 imposition of punitive damages in excess of the maximum criminal fine for the
7 same or similar conduct, which thereby infringes upon the Due Process Clause
8 of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the
9 Fourteenth Amendment of the United States Constitution;

10 (g) the procedures pursuant to which punitive damages are awarded permit the
11 imposition of excessive fines in violation of the Eighth Amendment of the
12 United States Constitution;

13 (h) the award of punitive damages to the plaintiff in this action would constitute a
14 deprivation of property without due process of law; and

15 (i) the procedures pursuant to which punitive damages are awarded permit the
16 imposition of an excessive fine and penalty.

17 42. Defendants expressly reserve the right to raise as an affirmative defense that
18 Plaintiff has failed to join all parties necessary for a just adjudication of this action, should
19 discovery reveal the existence of facts to support such defense.

20 43. Defendants reserve the right to raise such other affirmative defenses as may be
21 available or apparent during discovery or as may be raised or asserted by other defendants in
22 this case. Defendants have not knowingly or intentionally waived any applicable affirmative
23 defense. If it appears that any affirmative defense is or may be applicable after Defendants
24 have had the opportunity to conduct reasonable discovery in this matter, Defendants will
25 assert such affirmative defense in accordance with the Federal Rules of Civil Procedure.
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REQUEST FOR JURY TRIAL

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury on all issues appropriate for jury determination.

WHEREFORE, Defendants aver that Plaintiff is not entitled to the relief demanded in the Plaintiff's Complaint, and these Defendants, having fully answered, pray that this action against them be dismissed and that they be awarded their costs in defending this action and that they be granted such other and further relief as the Court deems just and appropriate.

This 17th day of February, 2016.

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**Attorney for Defendants C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.**

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on February 17, 2016, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

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